

REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 29-48) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recognized that the present invention provides hygienic protection for endoscopes, so that such instruments, which have become highly valuable medical diagnostic and procedure tools, can be readily re-used on a patient following recent use on a prior patient. Endoscopes, lacking proper protection against contamination, must generally be dismantled after each use and thoroughly cleaned, which is both time-consuming and quite expensive.

The present invention, as now claimed, provides hygienic protection for an endoscope, which includes a cover, which is closed at its distal end and which is transparent for optical information, at least on the front side thereof, with the cover able to be rolled thereon in a direction of the axis of the endoscope. One or more working channels for the endoscope extend in a parallel position in relation to the endoscope and terminate in an open manner on the distal end of the cover – the working channel being connected only to the distal end of the cover. The working channels are positioned between the outside of the endoscope and the inner side of the cover. There is only a single vacuum channel, having one or more openings, which terminates at the inside of the cover in a direction facing the endoscope, which is a “dedicated” vacuum and is in addition to the separate working channels. As explicitly claimed, the working channel(s) and the single vacuum

channel are entirely separate from one another, in that the one or more working channels are not useful for use as a vacuum channel, and vice versa, in contrast to the applied prior art.

More particularly, the single vacuum channel of the presently claimed invention terminates in an open manner within the envelope of the endoscope protection and can have additional side openings. These side openings advantageously terminate at the inside of the cover on the side of the cover (*i.e.*, an inner side or inner surface of the cover) facing in a direction of the endoscope. When a vacuum is applied to this channel, the air located between the cover and endoscope shaft is sucked out with the consequence being that the cover is drawn firmly onto the endoscope. The vacuum is then maintained during the examination. Thus, a fixed connection between the cover and endoscope is produced advantageously and rapidly after the endoscope has been introduced into the cover, which is dimensioned somewhat larger in the interior diameter, preferably in the proximal part.

During application of the hygiene protection, one hand of the medical practitioner fixes the freely movable working channels and the vacuum channel on the endoscope shaft, while the practitioner's other hand rolls on the cover above the channels. The combination of a protective cover, with its own working channels, extends outside of the endoscope with the protective cover and the working channels being connected to one another in the distal region of the cover in an airtight and germ-free manner. For attachment of the protection cover in accordance with the presently-claimed invention, the

distal end of the cover is pushed onto the endoscope, so that the front face, which is transmissible for optical information, is correctly positioned, *i.e.*, positioned parallel to the distal end of the endoscope. The optical contact between the endoscope and the transparent front face of the cover is preferably produced by means of a fluid, such as microscope immersion oil, which ideally has the same refractive index as the lens of the endoscope.

As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and hygienically effective protection apparatus and related method for an endoscope, having one or more separate working channels and single, dedicated vacuum channels for enhanced hygiene, in which the openings of the vacuum channel terminates at the inside of the cover of the endoscope protection at an inner side of the cover facing in a direction toward the endoscope, either disclosed or suggested.

By the present amendment, Applicant has amended independent Claims 29, 47 and 48 (and dependent Claims 41-43, 45 and 46 for consistency) to now recite that the endoscope of the claimed invention now includes, or is “consisting of,” only a “single” vacuum channel, which is a “dedicated” vacuum channel, in that the sole vacuum channel is not, in the alternative, sometimes used as a working channel, as taught by the applied prior art. By dedicating a single channel for use solely as a vacuum channel, as opposed to using various channels for different purposes during different procedures, results in improved hygienic benefits.

Case law support for "closing" the language of one claim element, but not

otherwise closing the language of the entire claim, is found in *Mannessman Demag Corp. v. Engineered Metal Products Co., Inc.*, 793 F.2d 1279, 230 USPQ 45, 46 (Fed. Cir.1986) ("The court correctly observed that the phrase 'consisting of' appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause (a). The court correctly declined to read this usage of 'consisting of' as excluding all other elements from the claim as a whole."). In *Berenter v. Quigg*, 737 F.Supp. 5, 14 USPQ2d 1175-1176 (D.D.C. 1988), following the holding in *Mannessman*, the district court reversed the Board of Appeals affirmation of a final rejection and entered summary judgment against the PTO finding that "use of the open word 'comprising' in the preamble" still allowed the patent applicant to "close" the second step of a two-step method claim, by use of the phrase "consisting of" for that second step, without closing the entire method claim to the addition of further steps, not inconsistent with closure of the second recited method step.

Applicants therefore respectfully submit that independent Claims 29, 47 and 48, as well as all remains claims currently pending, which depend either directly or indirectly from either Claims 29, 47 or 48, are restricted, or "closed," to only a single vacuum channel, but are otherwise "open" to the inclusion of further, unspecified elements not inconsistent with having only a single vacuum.

Accompanying the present *Amendment in Response to the Final Office Action*, Applicant is filing a *Request for Continued Examination* and formal *Petition for a Three-Month Extension of Time* for response, and remitting all required fees. Accordingly, the "finality" of the last Office Action should be withdrawn and the foregoing amendments

presented herein entered, and considered on their merits, as a matter of right.

Turning now, in detail, to an analysis of the Examiner’s prior art rejection, in the most recent “final” Office Action, the Examiner has rejected independent Claims 29, 47 and 48 as being anticipated, pursuant to 35 U.S.C. §102(b), by Silverstein *et al.*, U.S. Patent No. 4,646,722, on the contention that Silverstein *et al.* discloses an endoscope (and related method) for hygiene protection, that includes a cover that is closed at a distal end and transmissible for optical information, a working channel extending parallel and being connected only to the distal end of the cover and positioned between an outer side of the endoscope via an inside of the cover, and a vacuum channel having at least one opening and terminating at the inside of the cover. The Examiner has also contended that Silverstein *et al.* teaches that the vacuum channel “is a different channel from said working channel,” thereby anticipating that claimed by the instant Applicant.

In reply to the Examiner’s 35 U.S.C. §102(b) anticipation rejection applying Silverstein *et al.*, the applied citation discloses an endoscope with a cover having channel (36), which is taught as being primary for biopsy purposes (*see*, Silverstein *et al.* at Col. 7, lines 20-31), but which may also be used as a vacuum channel. *See*, Silverstein *et al.* at Col. 7, lines 26-28 (“[T]he biopsy channel 36 can be used, as illustrated in FIG. 4, for suction by connecting the channel 36 to a conventional suction device through a valve 54.”). Silverstein *et al.* discloses the use of a biopsy channel as also being useful for a suction, or vacuum, channel, and consequently fails to teach or suggest the use of a single vacuum channel that is “dedicated” as being solely the vacuum channel, as now recited in

Applicant's independent Claims 29, 47 and 48. Applicant submits that use of a single, dedicated vacuum channel – a channel that is not used for biopsies or other purposes – provides enhanced hygiene and thereby yields an advance over the prior art.

In light of the foregoing, it is respectfully submitted that the Examiner's 35 U.S.C. §102(b) anticipation rejection, which applies Silverstein *et al.*, has been overcome and should now be withdrawn.

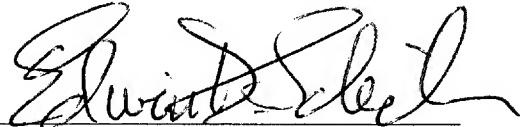
In view of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 29-48) recite a novel and hygienically effective protection apparatus and related method for an endoscope, having one or more separate working channels and single, dedicated vacuum channels for enhanced hygiene, in which the openings of the vacuum channel terminates at the inside of the cover of the endoscope protection at an inner side of the cover facing in a direction toward the endoscope, which is patentably distinguishable over the prior art. According-

ly, withdrawal of the outstanding rejection and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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March 2, 2010

Enc.: 1. Petition for Three-Month Extension of Time for Response;

2. *Request for Continued Examination*, pursuant to 37 C.F.R. §1.114; and,

3. EFT for \$960.00 (*Request for Continued Examination* filing fee + Three-Month Extension Fee);

The Commissioner for Patents is hereby authorized to charge the Deposit Account of Applicant's Attorney (Account No. 19-0450) for any fees or costs pertaining to the prosecution of the above-identified patent application, but which have not otherwise been provided for.